 4840-CH-503

 Rheumatoid Factor

**RHEUMATOID FACTOR**

**ABBOTT ARCHITECT**

**Principle**

Rheumatoid Factor is an in vitro diagnostic assay for the quantitative determination of rheumatoid factor in human serum. The Rheumatoid Factor assay is a latex enhanced immunoturbidimetric assay that involves an antigen-antibody reaction between rheumatoid factor in the sample and denatured human IgG, which has been adsorbed to latex particles. The resulting agglutination is detected as an absorbance change (572 nm), with the magnitude of the change being proportional to the quantity of rheumatoid factor in the sample. The actual concentration is then determined by interpolation from a calibration curve prepared from calibrators of known concentration.

**Methodology:** Immunoturbidimetric.

**Clinical Significance**

Rheumatoid factor (RF) is an autoantibody against human immunoglobin G (IgG) commonly present at a high concentration in sera of patients with certain conditions, particularly in patients with rheumatoid arthritis.

The measurement of rheumatoid factor is useful in evaluating the diagnosis, effects of therapy, and prognosis of diseases such as rheumatoid arthritis, systemic lupus erythematosus, Sjogren’s syndrome, cryoglobulinemia, and chronic hepatopathy. This assay is designed to accurately and reproducibly measure serum rheumatoid factor using latex agglutination.

**Specimen Collection and Handling**

**Serum is the only acceptable specimen. Do not use plasma.**

**Serum:** Use serum collected by standard venipuncture techniques into glass or plastic tubes with or without gel barriers. Ensure complete clot formation has taken place prior to centrifugation. Centrifuge according to tube manufacturer’s instructions to ensure proper separation of serum from blood cells.

Some specimens, especially those from patients receiving anticoagulant or thrombolytic therapy, may take longer to complete their clotting processes. Fibrin clots may subsequently form in these sera and the clots could cause erroneous test results.

**Specimen Storage**



**NOTE:** Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

**Materials and Equipment Required**

* + **Abbott Architect Analyzers**
	+ **8G66 Rheumatoid Factor Reagent Kit**
	+ **8G67 Rheumatoid Factor Calibrator**
	+ **BioRad Immunology Control Levels 1 and 3**
	+ **Saline (0.85% to 0.90% NaCL for specimen dilutions**

**Reagent Handling and Storage:**

***CAUTION*:**

1. For in vitro diagnostic use.

2. Do not use components beyond the expiration date.

3. Do not mix materials from different kit lot numbers.

Do not mix reagents prepared at different times.

Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

R2 contains IgG sourced from human serum. Donor units of the serum have been tested and found to be nonreactive for HBsAg, HIV-1 RNA or HIV-1 Ag, anti-HCV, and anti-HIV-1/HIV-2.

• The following warning and precaution apply to R1 and R2: Contains sodium azide.

EUH032 Contact with acids liberates very toxic gas.

P501 Dispose of contents/container in accordance with local regulations.

These materials and their containers must be disposed of in a safe way.

**Reagent Handling**

Mix reagent cartridges by gentle inversion prior to placing on the instrument.

• Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate.

To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

**CAUTION:** Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration that could impact results.

**Reagent Storage**

• Reagent stability is 30 days if the reagent is uncapped and onboard.

• Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

R1 should be clear. R2 should appear milky.

Reagent Preparation:

8G66-21 Rheumatoid Factor is supplied as a liquid, ready-to-use, two-reagent kit which contains: **R1 & R2**



**Calibrator:** 8G67 Rheumatoid Factor Calibrator

**Quality Control:** Chemistry Controls

**Calibration**

**Frequency:**

Calibration is stable for 60 days for any one lot. Calibration is required with each change in reagent lot number.

**A new calibration is required:**

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Calibrator Required:** 8G67 Rheumatoid Factor Calibrator

**Reagents:**

8G67-02 Rheumatoid Factor Calibrator is prepared by diluting rheumatoid factor sera with a buffer solution containing 1% w/w bovine serum albumin to the concentration stated on each calibrator bottle. A preservative is also present.

**Calibrator Preparation:**

Rheumatoid Factor Calibrator requires no preparation prior to use.

**Calibrator Procedure:**

Calibration is performed by running a water blank and the Rheumatoid Factor Calibrator set. Water for the blank is provided by the instrument.

1. Verify that the correct calibrator values have been entered into the calibration file.

2. Allow calibrator to come to room temperature.

3. Mix bottle several times by gentle inversion.

4. Open bottle, place an appropriate amount of each calibrator in a separate sample cup, and place in the assigned positions.

5. Cap bottle tightly and return to refrigerated storage immediately after use.

6. Perform calibration as indicated in the **ARCHITECT System Operations Manual**.

**Quality Control:**

Abbott recommends, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions:

• Two levels of controls (normal and abnormal) are to be run every 24 hours.

• If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.

• If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory.

Recalibration may be necessary.

• Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Procedure**

For a detailed description of how to run an assay, refer to the **ARCHITECT System Operations Manual**.

**Reporting Results**

For Rheumatoid Factor, results are reported as IU/mL

**Reference Ranges**

**Serum**



**Critical Values: NA**

**Performance Characteristics**

Analytical Measuring Range (AMR) is 15.0 – 200 IU/mL

**Reportable Range**

The reportable range for Rheumatoid Factor is 15.0 to 2000.0 IU/mL. Results above 2000 IU/mL after a 1:10 dilution should be reported as >2000 IU/mL.

**Limit of Quantitation (LOQ)**

The LOQ for Rheumatoid Factor is 15.0 IU/mL.

**Dilution:**

**Serum:** Specimens with rheumatoid factor values exceeding 200.0 IU/mL are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

**Automated Dilution Protocol**

The Automated Dilution Protocol will perform a 1:5 or 1:10 dilution of the specimen and automatically correct the concentration by multiplying the result by the appropriate dilution factor.

**Manual Dilution Procedure**

Manual dilutions should be performed as follows:

• Use saline (0.85% to 0.90% NaCl) to dilute the sample.

• The operator must enter the dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor.

• If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

**NOTE:** If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

Error code 1054 indicates antigen excess. Dilute specimens and rerun. Specimens with rheumatoid factor values greater than 200.0 IU/mL up to 5,557.6 IU/mL were tested, and the results were flagged appropriately.

**Precision:**

The imprecision of the Rheumatoid Factor assay for results ≥ 30 IU/mL is ≤ 5% Total CV, and for results < 30 IU/mL the SD is ≤ 3 IU/mL.



#### Limitations of Procedure

N/A

**Interfering Substances**



Pharmaceuticals listed below may affect rheumatoid factor concentration.

1. Interferon Alfa-2a and methotrexate may decrease serum rheumatoid factor levels.

2. Penicillamine, pentopril, and timegadine have no significant effect on serum rheumatoid factor levels.

3. Methyldopa, oral contraceptives, and oxyphenisatin may increase serum rheumatoid factor levels.

4. Nonsteroidal anti-inflammatory drugs may decrease or have no significant effect on serum rheumatoid factor levels.

**References:**

1. ABBOTT ARCHITECT RF package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

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1. ABBOTT ARCHITECT RF Calibrator package insert

Abbott Laboratories

Diagnostics Division

1. Abbott ARCHITECT Operator’s Guide